

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Koji UKAI et al.

Application No.: 09/380,310

Confirmation No.: 2449

Filed: August 31, 1999

Art Unit: 1616

For: ORAL PHARMACEUTICAL PREPARATIONS  
DECREASED IN BITTERNESS BY MASKING

Examiner: M. Haghighatian

**INFORMATION DISCLOSURE STATEMENT**  
**(SUBMISSION CONCURRENT WITH A RULE 1.114 RCE APPLICATION)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

- ☐ a. Copies of cited U.S. patents and patent application publications are not included.  
Copies of foreign patent documents and non-patent literature are included.

☒ b. **Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited during prosecution of copending U.S. Application Nos. 10/407,226 and 10/203,687, and copies of those references were previously submitted to the USPTO.**

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☐ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☒ d. OTHER - The following additional information is provided for the Examiner's consideration. **References cited on the attached Form PTO/SB/08 which are not included herewith were previously cited during prosecution of copending U.S. Application Nos. 10/407,226 and 10/203,687, and copies of those references were previously submitted to the USPTO in those applications. JP 51-76413 A, JP 5-163154 A, JP 8-333245 A, JP 10-114683 A, JP 61-130239 A, JP 4-235136 A, and JP 4-346937 A were cited in the corresponding**

**Japanese Patent JP 3770518. JP 11-228450 (cited herein) corresponds to JP 3770518. The present application also corresponds to JP 2005-041887 (pending).**

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☒ e. **This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.**

☐ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

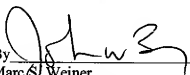
VI. PAYMENT OF FEES (check one box)☐ The required fee is listed on the attached Fee Transmittal.☒ **No fee is required.**

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: July 26, 2007

Respectfully submitted,

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(703) 205-8000  
Attorney for Applicant

## Attachment(s):

- ☒ PTO/SB/08  
☒ Document(s)  
☐ Foreign Search Report(s)  
☐ Fee  
☐ Other:

Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	09/380,310-Conf. #2449
		Filing Date	August 31, 1999
		First Named Inventor	Koji UKAI
		Art Unit	1616
		Examiner Name	M. Haghighatian
Sheet	1	of	2
		Attorney Docket Number	0425-0736P

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-5,466,464	11-14-1995	Masaki et al.	
	AB*	US-4,725,440	02-16-1988	Ridgway et al.	
	AC*	US-5,955,106	09-21-1999	Moeckel et al.	
	AD*	US-6,455,053-B1	09-24-2002	Okada et al.	
	AE*	US-6,743,443-B1	06-01-2004	Furitsu et al.	
	AF*	US-6,656,492	12-2003	Kajiyama et al.	
	AG*	US-5,962,535-A	10-1999	Miyamoto et al.	
	AH*	US-5,489,436-A	02-1996	Hoy et al.	
	AI*	US-5,084,278-A	01-1992	Mehta	
	AJ*	US-5,077,053-A	12-1991	Kunczewitch et al.	
	AK*	US-6,214,386-A	04-2001	Santus et al.	
	AL*	US-5,576,014	11-1996	Mizumoto et al.	
	AM*	US-6,586,004	07-2003	Shimizu et al.	
	AN*	US-6,576,677-B1	06-10-2003	Ukai et al.	
	AO*	US-5,827,507	10-1998	Oshima et al.	
	AP*	US-5,874,074	02-1999	Smith	
	AQ*	US-5,763,449-A	06-09-1998	Anaebonam et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figure Appear	1*
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
	BA	JP-41-1106353	04-1999			
	BB	JP-10-0036292-A	02-10-1998			✓
	BC	JP-60-204712-A	10-16-1985			✓
	BD	JP-03-005418-A	01-11-1991			✓
	BE	JP-09-143100-A	06-03-1997			✓
	BF	JP-03-287535-A	12-18-1991			✓
	BG	JP-04-018015-A	01-22-1992			✓
	BH	EP-0 753 296-A2	01-15-1997			
	BI	EP-0 748 628-A2	12-18-1996			
	BJ	WO-99/18936-A1	04-22-1999			✓
	BK	JP-11-199517-A	07-27-1999			✓
	BL	EP-0 590 963-A1	04-06-1994			
	BM	EP-0 691 122-A2	01-10-1996			
	BN	JP-2807346-B2	07-24-1998			✓
	BO	JP-5-271054-A	10-19-1993			✓
	BP	JP-9-48726-A	02-18-1997			✓
	BQ	JP-6-218028-A	08-09-1994			✓
	BR	JP-8-19589-A	01-23-1996			✓
	BS	EP-0 922 464-A1	06-16-1999			
	BT	WO-00/25754-A2	05-11-2000			
	BU	WO-00/20033-A1	04-13-2000			✓
Examiner Signature				Date Considered		

Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	09/380,310-Conf. #2449
		Filing Date	August 31, 1999
		First Named Inventor	Koji UKAI
		Art Unit	1616
		Examiner Name	M. Haghighatian
Sheet	2	of	2
		Attorney Docket Number	0425-0736P

	BV	EP-1 120 120-A1	08-01-2000		
	BW	JP-51-76413	07-02-1976		✓
	BX	JP-5-163154-A	06-29-1993		✓
	BY	JP-8-333245-A	12-17-1996		✓
	BZ	JP-10-114663-A	05-06-1998		✓
	BA1	JP-61-130239-A	06-18-1986		✓
	BB1	JP-4-235136-A	08-24-1992		✓
	BC1	JP-4-346937-A	12-02-1992		✓
	BD1	JP-11-228450-A	08-24-1999		✓
	BE1	JP-2005-041887	02-17-2005		✓

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.90(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IPW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	1998 Physician Desk Reference, page 1203.	
	CB	WADE and WELLER-Editors: Handbook of Pharmaceutical Excipients, Povidone, Page 392, 1994.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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